Remarks

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

Filed herewith is a 37 C.F.R. §1.131 Declaration of Gregory H. Altman, Ph.D. ("Altman Declaration") and Exhibits A and B. Also filed herewith is a 37 C.F.R. §1.132 Second Declaration of David Kaplan, Ph.D. ("Second Kaplan Declaration").

Claims 1 is amended. Claim 3 is canceled. Claims 32-49 are withdrawn. Support for the amendments to the claims is found at paragraphs [0026], [0030], and throughout the specification.

The rejection of claims 1 and 4-31 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement is respectfully traversed. Applicants disagree with the U.S. Patent and Trademark Office's ("PTO") suggestion that paragraph [0022] is directed only to a preferred embodiment. The first sentence of paragraph [0022] states:

> ""Natural" silk fibroin fibers are produced by an insect, such as a silkworm or a spider and possess their native, as formed protein structure."

Furthermore, paragraph [00112] states that:

> "The fibroin fibers in the samples in all the above Tables and Figures (and throughout the disclosure) are native (i.e., the fibers are not dissolved and reformed); dissolution and reformulation of the fibers results in different fiber structure with different mechanical properties after reforming."

Therefore, the specification and claims comply with the written description requirement and the rejection under 35 U.S.C. §112, first paragraph, is improper and should be withdrawn.

The rejection of claims 1, 2, and 4-31 under 35 U.S.C. §103(a) for obviousness over U.S. Patent No. 7,285,637 to Armato et al. ("Armato"), and if necessary U.S. Patent No. 6,303,136 to Li et al. ("Li") and U.S. Patent No. 5,736,399 to Takezawa et al. ("Takezawa") is respectfully traversed.

Applicants respectfully point out that the rejection under 35 U.S.C. §103(a) for obviousness is improper because the *prima facie* case for obviousness has not been established

because the Armato reference can be antedated, therefore, Armato was not available to the inventors as a reference at the time of invention.

Applicants respectfully point out that the rejection based on Armato is relevant to subject matter that is, in fact, disclosed in the earlier priority document (Application No. 10/008,924 filed November 16, 2001, now issued U.S. Patent No. 6,902,932). Applicants are entitled to the earlier priority date as explained below.

The PTO relies on the disclosure of Armato relating to constructs composed of degummed silk fibroin fibers for forming structures suitable for implant biomaterials, cell scaffolds, or tissue engineering applications (Office Action, page 4, lines 4-14). While Applicants do not believe the subject matter of Armato is equivalent to the claimed invention (at least because the Armato fibers are partially dissolved and not in their native protein structure), Applicants respectfully point out that silk fiber matrices (yarns) are disclosed in the earlier priority document of the instant application and that, therefore, Applicants are entitled to claim priority to the parent application for purposes of traversing the obviousness rejection based on Armato.

The Foreign Application Priority Data for Armato is an Italian language application (VR00A0096) filed in Italy on October 2, 2000. The corresponding PCT application (PCT/IT01/00501) was filed in English designating the U.S. on September 28, 2001. Applicants respectfully point out that the portion of the claimed invention which Armato purportedly makes obvious was made prior to the date Armato became an effective 35 U.S.C. 102(e) anticipatory reference which was September 28, 2001, the date of filing of the PCT application that corresponds with Armato.

Applicants, by way of the Antedating Declaration under 37 C.F.R. § 1.131 of Gregory H. Altman, Ph.D. ("Altman Declaration"), demonstrate, for purposes of traversing the obviousness rejection based on Armato, completion of the invention of Application No. 10/008,924 filed November 16, 2001, now issued U.S. Patent No. 6,902,932, prior to September 28, 2001. Therefore, Armato is antedated and can no longer be considered a 35 U.S.C. 102(e) anticipatory reference. Consequently, Armato was not available as a prior art reference.

Applicants also note that the Armato reference refers to the product produced as a fabric and that the PTO relies on this assertion (Office Action, page 4, lines 4-14). However Applicants point to the Second Declaration of David Kaplan, Ph.D., under 37 C.F.R. § 1.132

("Second Kaplan Declaration") to show that Armato's use of the word "fabric" is different from the fabric of the present invention and that although "Armato suggest that "[t]he use of textile methods would theoretically be possible to weave using merely degummed silk fibroin fibers in order to obtain a flexible fabric." (Armato, col. 2, lines 20-22) Armato does not disclose production of or use of fibers that could be used to produce a fabric comprising one or more individual yarns, wherein said yarn comprises one or more sericin-extracted fibroin fibers that retain their native protein structure and have not been dissolved and reconstituted, said fibers being biocompatible and non-randomly organized, wherein said yarn promotes ingrowth of cells around said fibroin fibers and is biodegradable as required by the present claims." (See Second Kaplan Declaration ¶ 9)

And that "[t]he fibers treated with formic acid solution and the resulting mesh produced by the drying process, as taught by Armato, is incapable of forming a yarn suitable to produce a fabric comprising one or more individual yarns, wherein said yarn comprises one or more sericin-extracted fibroin fibers that retain their native protein structure and have not been dissolved and reconstituted, said fibers being biocompatible and non-randomly organized, wherein said yarn promotes ingrowth of cells around said fibroin fibers and is biodegradable." (See Second Kaplan Declaration ¶ 8) Therefore, the obviousness rejection based on Armato is improper and should be withdrawn.

In view of the foregoing, having overcome all the pending rejections, Applicants respectfully submit that all claims are in condition for allowance. Early and favorable action is requested.

In the event that any additional fees are required, the Commissioner is hereby is authorized to charge Nixon Peabody LLP deposit account No. 50-0850. Any overpayments should also be deposited to said account.

Date: August 8, 2008

Respectfully submitted,

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